DOCKET NO.: OVIT-0283 **PATENT**

Application No.: 10/771,077

Preliminary Amendment - First Action Not Yet Received

Amendments to the Specification:

Please amend paragraph 28 as follows:

[0028] Figure 9 is a representative FTIR spectrum of bone graft material of the

present invention vs. β-TCP (beta-TCP) and Predicate.

Please amend paragraph 46 as follows:

[0046] It will be appreciated that in some embodiments of the overall porosity of

materials prepared in accordance with this invention the overall porosity will be high. This

characteristic is measured by pore volume, expressed as a percentage. Zero percent pore

volume refers to a fully dense material, which, perforce, has no pores at all. One hundred

percent pore volume cannot meaningfully exist since the same would refer to "all pores" or

air. Persons skilled in the art understand the concept of pore volume, however and can easily

calculate and apply it. For example, pore volume may be determined in accordance with W.

D. Kingery, Introduction to Ceramics, 1960 p. 416 (Wiley, 1060) Kingery, W.D.,

Introduction to Ceramics, Wiley Series on the Science and Technology of Materials, 1st Ed.,

Hollowman, J.H., et al. (Eds.), Wiley & Sons, 1960, p. 409-417, who provides a formula for

determination of porosity. Expressing porosity as a percentage yields pore volume. The

formula is: Pore Volume= $(1-f_p)$ 100%, where f_p is fraction of theoretical density achieved.

Please amend paragraph 47 as follows:

[0047] Porosity is can be measured by Helium Pycnometry. This procedure

determines the density and true volume of a sample by measuring the pressure change of

helium in a calibrated volume. A sample of known weight and dimensions is placed in the

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pycnometer, which determines density and volume. From the <u>samples sample's</u> mass, the pycnometer determines true density and volume. From measured dimensions, apparent density and volume can be determined. Porosity of the sample is then calculated using (apparent volume - measured volume)/apparent volume. Porosity and pore size distribution may also be measured by mercury intrusion porosimetry.

Please amend paragraph 0069 as follows:

[0069] One embodiment was comprised of β-TCP, with a cation to anion ratio of Ca₃(PO₄)₂; and medical grade Type I bovine collagen, manufactured in the following manner. Inorganic scaffolds were made using the RPR process disclosed in U.S. Patent Nos. 5,939,039 and 6,325,987. The resultant inorganic scaffolds were crushed and sieved to obtain morsels in the size range of .25mm-4mm. The morsels were added to a fibrous collagen slurry in a wet processing room and the resultant slurry was further mixed and casted/molded into various shapes in a cleanroom. The shapes were freeze-dried and crosslinked using dihydrotestosterone Dehydrothermal (DHT) treatment to produce resultant bone graft material shaped products.

Please amend paragraph 0078 as follows:

[0078] In addition to histology, half of each specimen from the animal study was utilized for biomechanical indentation testing. In brief, a flat-head indentor with a diameter equal to half the diameter of the defect (e.g., 5mm diameter indentor for 10mm humeral

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defects and 4mm diameter indentor for 8mm femoral condyle defects) was lowered (compression compressed) into the center of the defect in order to evaluate the structural properties of the repaired defect at 3, 6, 12, and 24-week time points. For comparison purposes, the indentor was also lowered in an area adjacent to the defect to evaluate the structural properties of the adjacent bone. Ultimate indentation load, yield load, stiffness, and ultimate indentation strength were quantified.